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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,650	07/07/2003	Yong Hua Zhu	LOMAU.122C1	7638
20995	7590	06/28/2007		
KNOBBE MARTENS OLSON & BEAR LLP			EXAMINER	
2040 MAIN STREET			HAND, MELANIE JO	
FOURTEENTH FLOOR				
IRVINE, CA 92614				
			ART UNIT	PAPER NUMBER
			3761	
			NOTIFICATION DATE	DELIVERY MODE
			06/28/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
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Office Action Summary

Application No.

10/614,650

Applicant(s)

ZHU ET AL.

Examiner

Melanie J. Hand

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2007.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-15, 17-22 and 24-35 is/are pending in the application.
- 4a) Of the above claim(s) 2-9, 11-15, 17-20 and 25-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10, 21, 22, 24, 34, 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 10, 21, 22, 24 and 34 have been considered but are moot in view of the new ground(s) of rejection.

Briefly, the prior art of Hammerslag anticipates the claims as amended because Hammerslag teaches an embodiment of an applicator 80 in which a patch is pre-attached to said applicator and wherein the first and second lumens do not move with respect to one another, thus the distal opening of the first lumen is permanently maintained at a position distal of a second distal opening. Further, paragraphs 0040-0042 are not sufficient support for the amendment to claim 21. Those paragraphs describe maintaining the patch in place with respect to the first distal opening, and do not provide support for a first distal opening permanently maintained at a position distal of a second distal opening. Figs. 3 and 4 are also not adequate support because drawings are by their nature unable to depict the permanent maintenance of an object in position relative to another, as such depiction requires "snapshots" of the relative positions over time, which one drawing cannot provide.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10, 21, 22, 24, 34 and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

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which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 21 as amended is not supported in the disclosure, as there is no support for the permanent maintenance of a first lumen distal opening at a position distal of a second distal opening. Claims 10, 22, 24, 34 and 35 depend from claim 21 and are thus also rejected. Claim 35 is further rejected because, while there is support for the wound cover having a diameter greater than the disclosed release rod 90, there is no explicit support for the limitation that the diameter of the wound cover is greater than the diameter of the second lumen.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 10, 21, 22, 24, 34 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Hammerslag et al ('194).

With respect to **Claim 10**: Hammerslag teaches a tissue closure device comprising an elongate body with a first portion 80 and a second portion 270 having a lumen, each portions having a distal end; the second portion 270 cannot be moved distally (i.e. said portion is a rigid fixture) relatively to the first portion distal end beyond the minimum distance and is arranged concentrically around the first portion 80. That is, the first and second portions are rigidly connected to one another so as to always move as a single elongate unit. (Col. 13, lines 62-67, Col. 14, lines 1-5)

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With respect to **Claim 21**: Hammerslag teaches a tissue closure device comprising an elongate body comprising a first lumen 80 having a first distal opening and a second lumen 270 having a second distal opening, the lumens being arranged so that a longitudinal space is defined between the first and second distal openings as indicated in Fig. 11. Wound cover member 88 is releasably connected to the elongate body at said first distal opening, as is also seen in Fig. 11. The first distal opening is permanently maintained at a position distal of the second distal opening prior to advancement and release of patch 88 and the first lumen 80 and second lumen 270 do not communicate with one another. (Col. 13, lines 62-67, Col. 14, lines 1-5) In light of the rejection of claim 21 under 35 U.S.C. 112, Hammerslag is applied herein as prior art anticipating claim 21.

With respect to **Claim 22**: The second lumen 270 is configured as an applicator to communicate a flowing fluid therethrough, i.e. the fluid that forms patch 88. (Col. 2, lines 21-24, Col. 4, lines 21-23, Col. 13, lines 62-64)

With respect to **Claims 24,34**: Hammerslag teaches that the applicator of the instant invention additionally comprises a release rod 26 sized and configured to slide through first lumen 80 and into contact with adhesive 16 (or alternatively, wound cover member 88). (Col. 4, lines 20-22)

With respect to **claim 35**: The wound cover member, patch 88, has a diameter that is greater than a diameter of the second lumen distal opening. In light of the rejection of claim 35 under 35 U.S.C. 112, Hammerslag is applied herein as prior art anticipating claim 35.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand
Examiner
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June 21, 2007

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Tatyana', written over the printed name and title.